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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,144	12/29/2003	Daniel M. Gorman	DX01170K1	4801

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/749,144	GORMAN, DANIEL M.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Currently, claims 1-20 are pending.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 9 in part, 10-12, 13 and 14 in part, and 15, drawn to a method of modulating an activity of a cell with an agonist of DCRS9, wherein the agonist comprises an antibody, classified in class 424, subclass 130.1.

II. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 7, 9 in part, 10-12, 13 and 14 in part, 15 and 16, drawn to a method of modulating an activity of a cell with an antagonist of DCRS9, wherein the antagonist comprises an antibody or an soluble receptor of SEQ ID NO:12, classified in class 514, subclass 2.

III. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 9 in part, 10-12, 13 and 14 in part, and 15, drawn to a method of modulating an activity of a cell with an agonist of IL-17C, wherein the agonist comprises an antibody, classified in class 424, subclass 130.1.

IV. Claims 1 in part, 2, 3, 4 and 5 in part, 6, 9 in part, 10-12, 13 and 14 in part, and 15, drawn to a method of modulating an activity of a cell with an antagonist of IL-17C, wherein the antagonist comprises an antibody, classified in class 424, subclass 130.1.

V. Claims 1 in part, 2, 3, 4 in part, 9 in part, 10-12, and 13 in part, drawn to a method of modulating an activity of a cell with an agonist of DCRS9, wherein the agonist binds the nucleic acid of DCRS9, classified in class 514, subclass 44.

VI. Claims 1 in part, 2, 3, 4 in part, and 8, 9 in part, 10-12, 13 in part, and 17, drawn to a method of modulating an activity of a cell with an antagonist of DCRS9, wherein the antagonist comprises an anti-sense nucleic acid, or interference RNA, classified in class 514, subclass 44.

VII. Claims 1 in part, 2, 3, 4 in part, 9 in part, 10-12, and 13 in part, drawn to a method of modulating an activity of a cell with an agonist of IL-17C, wherein the agonist binds the nucleic acid of IL-17C, classified in class 514, subclass 44.

VIII. Claims 1 in part, 2, 3, 4 in part, and 8, 9 in part, 10-12, 13 in part, and 17, drawn to a method of modulating an activity of a cell with an antagonist of IL-17C, wherein the antagonist comprises an anti-sense nucleic acid, or interference RNA, classified in class 514, subclass 44.

IX. Claims 18 in part, 19 and 20, drawn to a method of diagnosing a disorder with a binding composition that specifically binds to a polypeptide of DCRS9, classified in class 435, subclass 7.1.

X. Claims 18 in part, 19 and 20, drawn to a method of diagnosing a disorder with a binding composition that specifically binds to a polypeptide of IL-17C, classified in class 435, subclass 7.1.

XI. Claims 18 in part, 19 and 20, drawn to a method of diagnosing a disorder with a binding composition that specifically binds to a nucleic acid of DCRS9, classified in class 435, subclass 6.

XII. Claims 18 in part, 19 and 20, drawn to a method of diagnosing a disorder with a binding composition that specifically binds to a nucleic acid of IL-17C, classified in class 435, subclass 6.

The inventions are distinct, each from the other because:

Invention I is distinct from invention II, wherein the method of Invention I is drawn to a method of modulating an activity of a cell with an *agonist* antibody of DCRS9, whereas the method of Invention II is drawn to a method of modulating an activity of a cell with an *antagonist* antibody or *soluble receptor* of DCRS9. The active ingredient in each method is distinct from each other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Inventions I and II are distinct from and unrelated to Inventions III and IV, wherein the methods of Inventions I and II are drawn to methods of modulating an activity of a cell with an agonist and antagonist antibody of *DCRS9*, respectively, whereas the methods of Inventions III and IV are drawn to methods of modulating an activity of a cell with an agonist and antagonist

antibody of *IL-17C*, respectively. The active ingredient in each method is distinct from each other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Invention III is distinct from invention IV, wherein the method of Invention III is drawn to a method of modulating an activity of a cell with an *agonist* antibody of IL-17C, whereas the method of Invention IV is drawn to a method of modulating an activity of a cell with an *antagonist* antibody of IL-17C. The active ingredient in each method is distinct from each other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Invention V is distinct from invention VI, wherein the method of Invention V is drawn to a method of modulating an activity of a cell with an *agonist* binding the nucleic acid of DCRS9, whereas the method of Invention VI is drawn to a method of modulating an activity of a cell with an *antagonist* binding the nucleic acid of DCRS9. The active ingredient in each method is distinct from each other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Inventions V and VI are distinct from and unrelated to Inventions VII and VIII, wherein the methods of Inventions V and VI are drawn to methods of modulating an activity of a cell with an agonist and antagonist binding the nucleic acid of *DCRS9*, respectively, whereas the methods of Inventions VII and VIII are drawn to methods of modulating an activity of a cell with an agonist and antagonist binding the nucleic acid of *IL-17C*, respectively. The active ingredient in each method is distinct from each other, and cannot be used in the other methods. Therefore, non-coextensive searches are required.

Invention VII is distinct from invention VIII, wherein the method of Invention VII is drawn to a method of modulating an activity of a cell with an *agonist* binding the nucleic acid of IL-17C, whereas the method of Invention VIII is drawn to a method of modulating an activity of a cell with an *antagonist* binding the nucleic acid of IL-17C. The active ingredient in each method is distinct from each other, and cannot be used in the other method. Therefore, non-coextensive searches are required.

Inventions I-IV are distinct from and unrelated to Inventions V-VIII, wherein the methods of Inventions I-IV are drawn to methods of modulating an activity of a cell with *an antibody* or *a soluble receptor*, whereas the methods of Inventions V-VIII are drawn to methods of modulating an activity of a cell with *a nucleic acid*. The active ingredient in each method is distinct from

and unrelated to each other, and cannot be used in the other methods. Therefore, non-coextensive searches are required.

Invention IX is distinct from and unrelated to invention X, wherein the method of Invention IX is drawn to a method of diagnosing a disorder with a binding composition to a polypeptide of *DCRS9*, whereas the method of Invention X is drawn to a method of diagnosing a disorder with a binding composition to a polypeptide of *IL-17C*. They are for detecting different molecules, and thus involve different active agents, and are for different purposes, wherein each agent cannot be used in the other method, and each method does not require the other. Therefore, non-coextensive searches are required.

Inventions IX and X are distinct from and unrelated to Inventions XI and XII, wherein the methods of Inventions IX and X are drawn to methods of diagnosing a disorder with a binding composition to a *polypeptide*, whereas the methods of Inventions XI and XII are drawn to methods of diagnosing a disorder with a binding composition to a *nucleic acid*. The active ingredient and method steps are completely different in each method, and one cannot be used in the other method, and one does not require the other. Therefore, non-coextensive searches are required.

Invention XI is distinct from and unrelated to invention XII, wherein the method of Invention XI is drawn to a method of diagnosing a disorder with a binding composition to a nucleic acid of *DCRS9*, whereas the method of Invention XII is drawn to a method of diagnosing a disorder with a binding composition to a nucleic acid of *IL-17C*. They are for detecting different molecules, and thus involve different active agents, and are for different purposes, wherein each agent cannot be used in the other method, and each method does not require the other. Therefore, non-coextensive searches are required.

Inventions I-VIII are distinct from and unrelated to Inventions IX-XII, wherein the methods of Inventions I-VIII are drawn to methods of *treatment*, whereas the methods of Inventions IX-XII are drawn to methods of *diagnosis*. They are for completely different purposes, and thus, the test object, active ingredient, method steps, and outcome in each method set are distinct from the other, and cannot be used in the other set of methods. Therefore, non-coextensive searches are required.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matters, restriction for examination purposes as indicated is proper.

2. Furthermore, regardless of which Invention applicants elect above, further **restriction** is required under 35 U.S.C. 121:

A. If any one of groups I-XII is elected, further elect *one* specific sequence with SEQ ID NO as applicable from the following: SEQ ID NO:11, 12, 23 or 24.

B. If any one of groups I-VIII is elected, further elect *one* specific interstitial lung disorder from those recited in claim 11, and they are: idiopathic pulmonary fibrosis; eosinophilic granuloma, and hypersensitivity pneumonitis.

The inventions are distinct, each from the other because of the following reasons:

With respect to group A, although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

With respect to group B, it comprises different interstitial lung disorders, which have distinct causes, clinical manifestations, treatment and outcomes, thus, non-coextensive search is needed for each type of the interstitial lung disorders.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of the invention from Groups I-XII, and an election of the invention from Groups A and B when applicable, to be examined even though the requirement be traversed (37 CFR 1.143), and (ii) identification of the claims encompassing the elected

invention. Applicant is advised that neither I-XII nor A-B is species election requirement; rather, each of I-XII and A-B is a restriction requirement.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Species election

This application contains claims directed to the following patentably distinct species: 1) there are five different clinical diseases/conditions recited in claims 1 and 9, and they are: psoriasis, IBD, interstitial lung disorder, asthma or allergy, and atherosclerosis; and 2) there are five different cell types recited in claims 2 and 10, and they are: monocytes or macrophages, dendritic cells, epithelial cells, endothelial cells, and keratinocytes. The species are independent or distinct because, with respect to 1), the recited diseases/conditions have distinct pathology, clinical manifestations, and distinct features in progress and prognosis, and involve distinct patient populations and different therapies, and thus, each requires a separate search of the prior art. With respect to 2), each cell type has distinct functional activity, distribution, and is involved in different disease/condition, and therefore, each requires a separate search of the prior art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Advisory Information

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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7/14/06